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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,994	09/26/2001	Audrey Goddard	P3121R1	2989

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GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER
KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 01/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,994	GODDARD ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *18-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Applicant's election without traverse of Group I, claims 1-17, in Paper No. 11 (18 November 2002) is acknowledged.

Claims 18-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

The preliminary amendments filed 14 January 2002 (Paper No. 7) and 14 February 2002 (Paper No. 9) have been entered in full. The sequence listing is free of errors and is entered in the file.

Information Disclosure Statement

The information disclosure statement filed 08 January 2002 *partially* fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because no dates were provided for the foreign patent documents. It has been placed in the application file, but the foreign patents information referred to therein has not been considered as to the merits. *The "U.S. Patent Documents" and "Other Disclosures" have been considered on the merits. Also, documents 40 and 41 have been considered on the merits; however, these documents are inappropriate for printing on the face of a patent and thus the printer has been instructed not to print these on the face of any patent issuing from this application.*

Applicant is invited to submit a new PTO-1449 form listing the foreign patent documents, *with dates listed*, for consideration.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4, 9, 10, 11, 12, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, the following phrase is confusing: "1 to 21 to about 262 of Figure 2". It is not clear what sequence is intended (1-21, 1-262, 21-262, etc.). It appears that this may be a typographical error, wherein "1 **or** 21 to about 262 of Figure 2)" was intended.

In claims 9 and 10, the following phrase is confusing: "Figure 2 9SEQ ID NO: 2)". Again, it appears that this may be a typographical error, wherein "Figure 2 (SEQ ID NO: 2)" was intended.

In claims 11 and 12, the phrase "stringent hybridization conditions" renders the claims indefinite. Stringency is relative, and the art does not recognize a single set of conditions as stringent. The specification also does not provide an unambiguous definition for the term. In the absence of a recitation of clear hybridization conditions (e.g., "hybridizes at wash conditions of **A** X SSC and **B** % SDS at **C**°C"), the claims fail to define the metes and bounds of the varying structures of polynucleotides recited in the claimed methods.

In claim 16, the following phrase is confusing: "a yeast cell of a Baculovirus-infected insect cell". It appears that this may be a typographical error, wherein "a yeast cell **or** a Baculovirus-infected insect cell" was intended.

Claim 17 is directed to a method of producing a PRO19598 polypeptide as defined in previous claims. However, claims 1 5, 7 and 12 specifically recite complementary sequences. It is unclear how one could produce a PRO19598 polypeptide from a complementary sequence, thus rendering claim 17 indefinite.

35 U.S.C. § 101 and 112, First Paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

The claims are directed to isolated nucleic acids having at least 80% identity to a nucleic acid encoding SEQ ID NO: 2 or the protein encoded by the cDNA deposited as ATCC Deposit No. PTA-1532. Dependent claims are directed to vectors and host cells comprising the isolated nucleic acids, and methods of recombinantly producing the encoded polypeptide. Finally, claims are presented to isolated nucleic acids that

hybridize to the aforementioned nucleic acids. The asserted utilities for the claimed invention are tied in its encoding an allegedly useful secreted protein (PRO19598), or hybridizing with a nucleic acid that encodes PRO19598. The specification asserts several utilities for PRO19598.

The specification states that PRO19598 specifically binds PRO3301 (e.g., p. 79 of specification). However, the specification does not present any potentially biological activities for either PRO19598 or PRO3301. Therefore, the asserted utility that PRO19598 is useful for binding PRO3301 is not substantial, because significant further research would be needed to determine the significance of the binding event.

The specification also asserts that PRO19598 sequences are useful in hybridization assays (as probes), chromosome and gene mapping (including in disease diagnostic assays), generation of anti-sense RNA and DNA, identification of proteins that bind PRO19598 (including agonists and antagonists), drug discovery, gene therapy, molecular markers, chromosome markers, tissue typing, therapeutic methods, ribozyme development, and in raising antibodies (see pp. 50-59). However, all of these asserted utilities are not specific or substantial. They are not specific, because any unrelated nucleic acid sequence can be used in the same way. Also, the asserted utilities are not substantial, because significant further research would be required to determine how to use the claimed invention in a real world sense. For example, although the specification asserts that the claimed sequences are useful in various diagnostic and therapeutic methods, the specification fails to provide a nexus between any specific disease and an alteration in level or form of the claimed sequences. The

amount of research required to establish such a nexus is staggering, and thus the asserted utilities are not substantial.

Beginning at p. 79, the specification describes experiments wherein cancerous tissues were screened for expression of PRO19598 (or its binding protein, PRO3301) by microarray technology. Specifically, expression was determined in cancerous tumor tissue and in a "universal normal control". The universal normal control was made from pooled epithelial cells of various tissues, including liver, kidney, and lung. At p. 81, the specification discloses that PRO3301 was overexpressed in colon, lung, breast and rectal tumor relative to the universal normal control. The specification asserts that the claims PRO19598 is useful as a cancer diagnostic based on these results. This is not found to be a substantial utility. Not all colon cancers are alike, and the specification fails to establish what type of colon, breast, etc. tumors were analyzed. Also, the specification does not clearly compare expression levels between tumor tissue and the *corresponding* healthy tissue. Also, not all tumors arise from epithelial cell layers, and thus the universal control is not a proper scientific control.

In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the

intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a polynucleotide encoding a protein which has undetermined function or biological significance. Until some actual and specific activity can be attributed to the protein identified in the specification as PRO19598 protein or the polynucleotides encoding it, the claimed invention is incomplete.

Claims 22-41 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1, 5, 7 are 9-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptides having at least 80% sequence identity with, or which hybridize to, a particular disclosed sequence. The claims do not require that the polypeptide possess any particular conserved structure or function, or other distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a partial structure in the form of a recitation of percent identity. The specification does not identify any particular portion of the structure that must be conserved, nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. The only adequately described species is a polypeptide comprising SEQ ID NO: 2. No active variants are disclosed. Accordingly, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the

method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

No claims are allowed.

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kotenko et al., 2001, J. Immunol. 166 :7096-7103. This reference discloses SEQ ID NO : 2 (see Figure 2). However, lithe reference does not qualify as prior art under 35 U.S.C. § 102, since the instant application disclosed SEQ ID NO: 2 in provisional

application 60/191015, filed 3/21/2000. Kotenko et al. indicates that SEQ ID NO : 2

binds IL-22; however, this utility was not suggested by the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Mon. - Thurs., 6:30 to 4:00, and alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ECK
January 16, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER